UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

Amanda Betty Sue Rousey, Individually and on behalf of the Estate of Peyton Bryan Rousey, deceased	)	**CIVIL ACTION NO.: 4:15-cv-1911**
Plaintiffs,	)	**COMPLAINT**
v.	)	**JURY DEMANDED**
GlaxoSmithKline LLC, Aurobindo Pharma Limited, and Aurobindo Pharma USA, Inc.	)	
Defendants.	)	

ORIGINAL COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, Amanda Betty Sue Rousey, individually and on behalf of the Estate of her son Peyton Bryan Rousey, ("Plaintiff"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") for compensatory damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Peyton Bryan Rousey as a result of her prenatal exposures to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiffs allege the following.

INTRODUCTION

1. Zofran is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea imaginable – that suffered as a result of chemotherapy or radiation treatments in cancer patients.

2. The U.S. Food and Drug Administration ("FDA") approved Zofran in 1991

for use in cancer patients who required chemotherapy or radiation therapy.

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" since at least January 1998 as an established safe and effective treatment for the very common side effect of a normal pregnancy - pregnancy-related nausea and vomiting - otherwise known as "morning sickness." GSK further marketed Zofran during this time as a "wonder drug" for pregnant women, despite having knowledge that GSK had never once undertaken a single study establishing that this powerful drug was safe or effective for pregnant mothers and their growing children *in utero.* Unlike another anti-nausea prescription drug available on the market – which is FDA-approved in the United States for treating morning sickness in pregnant women – GSK never conducted a single clinical trial establishing the safety and efficacy of Zofran for treating pregnant women before GSK marketed Zofran for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran. In short, GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies and buried any internal analyses of Zofran's teratogenic potential because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

4. As a result of GSK's nationwide fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women and in the 2000s became the number one most prescribed drug for treating morning sickness in the United States. These women ingested the drug because they innocently believed that Zofran was an appropriate drug for

use in their circumstance. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea. Zofran would never have become the most prescribed morning sickness drug in the United States, and Plaintiffs would never have taken it, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

5. By contrast, GSK knew that Zofran was unsafe for ingestion by expectant mothers. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity, intrauterine deaths and malformations in offspring, and further showed that Zofran's active ingredient transferred through the placental barrier of pregnant mammals to fetuses. A later study conducted in humans confirmed that ingested Zofran readily crossed the human placenta barrier and exposed fetuses to substantial concentrations. GSK did not disclose this material information to pregnant women or their physicians.

6. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date, including reports of the same congenital anomalies suffered by PEYTON BRYAN ROUSEY GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological and mechanistic studies that have demonstrated an elevated risk of developing Zofran-induced birth defects such as those suffered in this case. GSK has not disclosed this material information to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug since at least January 1998.

7. In 2012, GSK pled guilty to criminal charges lodged by the United States of America, through the Department of Justice, for its "off-label" promotion of its drugs for uses never approved by the FDA. In exchange for GSK's full performance of its criminal plea agreement with the United States and for certain other promises exchanged between GSK and the United States, the United States agreed not to prosecute GSK criminally for conduct relating to "GSK's sales, marketing and promotion of . . . Zofran between January 1998 and December 2004." (Agreement between United States and GSK, pp. 1-2, June 27, 2012.)

8. Around the same time, however, GSK entered civil settlements with United States that included more than $1 billion in payments to the federal government for its illegal marketing of various drugs, including Zofran specifically.

9. GSK's civil settlement agreement with the United States reports GSK's settlement of claims that GSK:

(a) "promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis and pregnancy-related nausea)"

(b) "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"

(c) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran"

(Settlement Agreement, p. 5, July 2, 2012.)

10. GSK's conduct has caused devastating, irreversible, and life-long consequences and suffering to innocent newborns and their families, like Plaintiffs herein.

11. Plaintiff's minor child, Peyton Bryan Rousey, was born and died on July 7, 2013 due to congenital defects after his mother, Plaintiff Amanda Betty Sue Rousey, was

prescribed and began taking Zofran beginning early in her first trimester of pregnancy and took it continuously from then through her third trimester to alleviate and prevent the symptoms of morning sickness.

12. Peyton Bryan Rousey was exposed to Zofran *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

13. Until recently, Ms. Rousey did not suspect Zofran as the cause of Peyton Bryan Rousey's congenital heart defects and subsequent death shortly after birth, having never been informed until recently that the safety of Zofran treatment in pregnant women has not been established and that Zofran was never FDA-approved to treat morning sickness.

14. Had Plaintiffs known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have taken Zofran, and her child would never had been injured as described herein.

15. Plaintiffs bring claims for compensatory damages, as well as equitable relief in an effort to ensure that similarly situated mothers-to-be are fully informed about the risks, benefits and alternatives attending drugs marketed for use in pregnant women, and such other relief deemed just and proper arising from injuries and birth defects as a result of exposure to Zofran.

JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 1332(d), where Plaintiffs' and Defendants' state of residence is different and diverse. This Court has personal jurisdiction over the parties because Defendants conduct substantial business in this State have had systematic and continuous contact within this State, and have

agents and representatives which can be found in this State. The amount in controversy exceeds $75,000 exclusive of interests and costs.

17. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391. GSK, upon information and belief, at all times relevant, engaged in the business of designing, testing, manufacturing, advertising, labeling, marketing, promoting, selling and distributing Zofran throughout the State of Texas.

PARTIES

18. Plaintiff, Amanda Betty Sue Rousey, is a citizen of the United States. She is the mother and representative of the Estate of Peyton Bryan Rousey. Plaintiffs reside in Muskogee, Oklahoma.

19. GSK is a limited liability company organized under the laws of the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is a Delaware corporation, and which has identified its principal place of business in Wilmington, Delaware.

20. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc. Glaxo, Inc. was the sponsor of the original New Drug Application ("NDA") for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran. The term GSK used herein refers to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcome Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale and/or distribution of Zofran.

21. At all relevant times, GSK conducted business in the State of Texas and has derived substantial revenue from products, including Zofran, sold in this State.

22. On information and belief, Defendant Aurobindo Pharma Limited ("Aurobindo Limited") is a corporation organized and existing under the laws of India having a registered office at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India, and having a principal place of business at Unit-VII, Sy.No. 411/P, 425/P, 434/P, 435/P, & 458/P, Plot No. S1 (Part), SEZ (Pharma), APIIC, Green Industrial Park, Mahaboob Nagar (DT), Jedcherla – 509 302, Andrha Pradesh, India.

23. On information and belief, Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation having a registered office, or place of business, at 6 Wheeling Road, Dayton, New Jersey 08810, and having a principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

24. On information and believe, Defendant Aurobindo USA is registered to transact business in Delaware and has an appointed a registered agent for service of process (The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801).

25. On information and belief, Defendant Aurobindo USA is a wholly owned subsidiary of Aurobindo Limited.

26. On information and belief, Defendant Aurobindo USA holds a Pharmacy – Wholesale License from the State of Delaware under License No. A4-0001240.

27. On information and belief, Defendant Aurobindo USA holds a Distributor/Manufacturer CSR License from the State of Delaware under License No. DM-0006550.

28. Defendant Aurobindo Pharma Limited ("Aurobindo Limited") and Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") are here and after collectively referred to as AUROBINDO DEFENDANTS.

PERTINENT BACKGROUND ON ZOFRAN

29. Zofran is a prescription drug indicated for the prevention of chemotherapy- induced nausea and vomiting, radiation therapy-induced nausea and vomiting and post-operative nausea and/or vomiting:

> **INDICATIONS AND USAGE**
>
> 1. Prevention of nausea and vomiting associated with highly emetogenic **cancer chemotherapy**, including cisplatin ≥ 50 mg/m2.
> 2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic **cancer chemotherapy**.
> 3. Prevention of nausea and vomiting associated with **radiotherapy** in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
> 4. Prevention of **postoperative nausea and/or vomiting**.

(GSK, Zofran Prescribing Information, Sept. 2014) (emphasis added.)

30. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting are called anti-emetics.

31. Zofran is part of a class of anti-emetics called selective serotonin 5HT3 receptor antagonists. The active ingredient in Zofran is ondansetron hydrochloride, which is a potent and selective antagonist at the 5-hydroxytryptamine receptor type 3 (5-HT3).

32. Although 5-hydroxytryptamine (5HT) occurs in most tissues of the human body, Zofran is believed to block the effect of serotonin at the 5HT3 receptors located along vagal afferents in the gastrointestinal tract and at the receptors located in the area postrema of the central nervous system (the structure in the brain that controls vomiting). Put differently, Zofran antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.

33. Zofran was the first 5HT3 receptor antagonist approved for marketing in the

United States. Other drugs in the class of 5HT3 receptor antagonist include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997), and Aloxi® (palonosetron) (FDA-approved 2003).

34. Zofran is available as an injection (2 mg/mL), a premixed injection (32 mg/50ml and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg); orally disintegrating tablets (4 mg and 8 mg) and an oral solution (4 mg/5 mL).

35. More specifically, GSK has obtained FDA approval for the following formations of Zofran:

a. NDA 20-007 – Zofran Injection (FDA approved January 4, 1991)

b. NDA 20-103 – Zofran Tablets (FDA approved December 31, 1992)

c. NDA 20-403 – Zofran Premixed Injection (FDA approved January 31, 1995)

d. NDA 20-605 – Zofran Oral Solution (FDA approved January 24, 1997)

e. NDA 20-781 – Zofran (a/k/a Zofran-Zydis) Orally Disintegrating Tablets (FDA approved January 27, 1999)

36. The FDA has never approved Zofran for the treatment of morning sickness or any other condition in pregnant women.

37. For GSK to market Zofran lawfully for the treatment of morning sickness in pregnant women, it must first adequately test the drug (including performing appropriate clinical studies) and formally submit to the FDA evidence demonstrating that the drug is safe and effective for treatment of morning sickness.

38. A team of the FDA's physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to: (a) review the company's data and evidence supporting its request for approval to market the drug; and (b) determine whether to approve the company's request to market the drug in the manner requested. Without first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

39. GSK has not performed any clinical studies of Zofran use in pregnant women. GSK, however, had the resources and know-how to perform such studies, and such studies were performed to support another prescription drug that, unlike Zofran, is FDA-approved for the treatment of morning sickness.

40. GSK also has not submitted to the FDA any data demonstrating the safety or efficacy of Zofran for treating morning sickness in pregnant women. Instead, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the treatment of morning sickness in pregnant women without applying for the FDA's approval to market Zofran to treat that condition or any other condition in pregnant women. This practice is known as "off-label" promotion, and in this case it constitutes fraudulent marketing.

41. At all relevant times, GSK was in the business of and did design, research, manufacture, test, package, label, advertise, promote, market, sell and distribute Zofran.

GSK's Knowledge That Zofran Presents an Unreasonable Risk of Harm to Babies Who Are Exposed to It During Pregnancy

Preclinical Studies

42. Since at least the 1980s, when GSK received the results of the preclinical studies that it submitted in support of Zofran's NDA 20-007, GSK has known of the risk that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies of Zofran in rats and rabbits, and reported that the rat and rabbit fetuses were exposed prenatally to Zofran during pregnancy.

43. The placental transfer of Zofran during human pregnancy at concentrations high enough to cause congenital malformations has been independently confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients. The average fetal tissue concentration of Zofran's active ingredient was 41% of the corresponding concentration in the mother's plasma.

44. GSK reported four animal studies in support of its application for approval of NDA 20-0007: (1) Study No. R10937 I.V. Segment II teratological study of rats; (2) Study No. R10873 I.V. Segment II teratological study of rabbits; (3) Study No. R10590 Oral Segment II teratological study of rats; (4) Study No. L10649 Oral Segment II teratological study of rabbits. These preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to show no harm to the fetus, but the data also revealed clinical signs of

toxicity, premature births, intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

45. Study No. R10937 was a Segment II teratological study of pregnant rats exposed to Zofran injection solution. Four groups of 40 pregnant rats (160 total) were reportedly administered Zofran through intravenous (I.V.) administration at doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. Clinical signs of toxicity that were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effects.

46. Study No. R10873 was a Segment II teratological study of pregnant rabbits exposed to Zofran injection solution. Four groups of 15 pregnant rabbits (60 total) were reportedly given Zofran doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. In this study, there was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower- dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in off-spring and fetuses were noted – namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

47. Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior, labored breathing, which is a symptom of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

48. Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in

the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

49. Even if animal studies do not reveal evidence of harm to a prenatally exposed fetus, that result is not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous teratogenic in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. But that is what GSK did.

Early Reports to GSK of Zofran-Related Birth Defects to GSK

50. At least as early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran by pregnant women.

51. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. These reports included congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

52. In many instances, GSK received multiple reports in the same month, the same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events. For two of those incidents, the impact on the baby was so severe that the baby died.

53. From 1992 to the present, GSK has received more than **200** reports of birth defects in children who were exposed to Zofran during pregnancy.

54. The most commonly reported birth defects arising from Zofran use during pregnancy and reported to GSK were congenital heart defects, though multiple other

defects such as orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

55. The number of events actually reported to GSK was only a small fraction of the actual incidents.

Epidemiology Studies Examining the Risk of Congenital Heart Defects in Babies Who Were Exposed to Zofran During Pregnancy

56. Epidemiology is a branch of medicine focused on studying the causes, distribution, and control of diseases in human populations.

57. Three recent epidemiological studies have examined the association between prenatal exposure to Zofran and the risk of congenital heart defects in babies. These studies include: (1) Pasternak, et al., *Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes*, New England Journal of Medicine (Feb. 28, 2013) (the "Pasternak Study"); (2) Andersen, et al., *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations— A Register Based Nationwide Control Study*, presented as International Society of Pharmaco-epidemiology, Montreal, Canada (2013) (the "Andersen Study"); and (3) Danielsson, et al., *Ondansetron During Pregnancy and Congenital Malformations in the Infant* (Oct. 31, 2014) (the "Danielsson Study").

58. Each of these studies includes methodological characteristics tending to bias its results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding these characteristics biasing the results toward the null hypothesis, all three studies show elevated risk ratios for cardiac malformations, including risk ratios greater than 2.0. In other words, the studies report that a mother exposed to Zofran had more than a doubled risk of having a baby with a congenital heart defect as compared to a mother who did not ingest Zofran during pregnancy.

59. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were

608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

60. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen study examined the relationship between Zofran use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester, and prescription data were obtained from the National Prescription Registry. The Andersen study reported that mothers who ingested Zofran during their first- trimester of pregnancy were more likely than mothers who did not to have a child with a congenital heart defect, and had a two- to four-fold greater risk of having a baby with a septal cardiac defect.

61. The Danielsson Study investigated risks associated with Zofran use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish Register of Prescribed Drugs to identify 1,349 infants born to women who had

taken Zofran in early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants, and 43,658 had malformations classified as major (2.9%). Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The Danielsson study reported a statistically significantly elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not. The results reported that the mothers who took Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran during pregnancy.

62. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnancy women.

GSK's Failure to Warn of the Risk of Birth Defects Associated with Prenatal Exposure to Zofran

63. Under federal law governing GSK's drug labeling for Zofran, GSK was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e)

(emphasis added).

64. GSK was also required to list adverse reactions that occurred with other drugs in the same class as Zofran. *Id.* § 201.57(g).

65. In the context of prescription drug labeling, "an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *Id.*

66. Federal law also required GSK to revise Zofran's labeling "**to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.**" *Id.* § 201.57(e) (emphasis added).

67. GSK has received hundreds of reports of birth defects associated with the non-FDA-approved use of Zofran in pregnant women. GSK has failed, however, to disclose these severe adverse events to healthcare providers or expectant mothers, including Ms. Rousey and her prescribing healthcare provider.

68. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free to add or strengthen – without prior approval from the FDA – a contraindication, warning, precaution, or adverse reaction.

69. GSK thus had the ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to do so.

70. Under 21 C.F.R. § 201.128, "if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

71. At least as of 1998, GSK knew well from its off-label promotion and payments to doctors, and its conspicuous increase in revenue from Zofran, and its market

analyses of prescription data, that physicians were prescribing Zofran off-label to treat morning sickness in pregnant women and that such usage was associated with a clinically significant risk or hazard – birth defects.

72. GSK had the ability and obligation to state prominently in the Indications and Usage section of its drug label that there is a lack of evidence that Zofran is safe for the treatment of morning sickness in pregnant women. GSK failed to do so, despite GSK's knowledge that (a) the safety of Zofran for use in human pregnancy has not been established, and (b) there have been hundreds of reports of birth defects associated with Zofran use during pregnancy, and (c) epidemiology studies report an increased risk of birth defects in babies exposed to Zofran during pregnancy.

73. From 1993 to the present, despite mounting evidence of the birth defect risk, GSK's prescribing information for Zofran has included the same statement concerning use of Zofran during pregnancy:

> "**Pregnancy: Teratogenic Effects**: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed."

74. By contrast, the Product Monograph for Zofran in Canada states "**the safety of ondansetron for use in human pregnancy has not been established**," and that "**the use of ondansetron in pregnancy is <u>not</u> recommended**."

75. In the United States and in this Commonwealth specifically, GSK has at all relevant times failed to include any warning disclosing any risks of birth defects arising from Zofran use during pregnancy in Zofran's prescribing information or other product labeling.

76. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers the FDA's pregnancy categorization scheme applicable to prescription drugs in the United States. The FDA has established five categories to indicate the potential of a drug to cause birth defects if used during pregnancy. The current system of pregnancy labeling consists of five letter-categories (A, B, C, D, and X, in order of increasing risk).

77. GSK had the ability, and indeed was required, to update Zofran's label to reflect at best a Pregnancy Category D designation or alternatively a Category X designation for Zofran:

> **Pregnancy Category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans**, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life- threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See "Warnings and Precautions" section. Under the "Warnings and Precautions" section, **the labeling must state: "[drug] can cause fetal harm when administered to a pregnant woman. . . . If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**
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> 21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).
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> **Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both**, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See `Contraindications' section." Under "Contraindications," **the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. . . . (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.**"
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> *Id.* § 201.57(f)(6)(i)(e) (emphasis added).

78. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based more than 200 reports to GSK of birth defects, as well as epidemiology studies, and placental-transfer studies reporting on Zofran's teratogenic risk. GSK has never updated Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

79. The FDA recently promulgated a final rule declaring that, as of June 2015, it will require pharmaceutical manufacturers to remove the current A, B, C, D, or X pregnancy categorization designation from all drug product labeling and instead summarize the risks of

using a drug during pregnancy, discuss the data supporting that summary, and describe relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In promulgating this rule, the FDA "determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk."

80. In summary, Plaintiff was exposed to Zofran, GSK marketed and sold Zofran without adequate warning to healthcare providers and consumers that Zofran was causally associated with an increased risk of birth defects, and that GSK had not adequately tested Zofran to support marketing and promotion it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

81. Plaintiffs hereby demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiffs and similarly situated mothers and mothers-to-be, as GSK's wrongful conduct alleged herein is continuing. Plaintiffs further demand that GSK fully and fairly comply, no later than June 2015, to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the risks of using Zofran during pregnancy, fully and accurately describe the data supporting that summary, and fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.

GSK's Fraudulent, Off-Label Promotion of Zofran for the Treatment of Morning Sickness in Pregnant Women

82. At all relevant times, GSK has known that the safety of Zofran for use in human pregnancy has not been established.

83. But with more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy-related nausea, the absence of a prescription medication that was approved by the FDA for pregnancy-related nausea presented an extremely lucrative business opportunity for GSK to expand its sales of Zofran,

which before its patent expiration in 2006 was one of the most expensive drugs available in the U.S. market. GSK seized that opportunity, but the effect of its conduct was tantamount to experimenting with the lives of unsuspecting mothers-to-be and their babies in the United States and in this Commonwealth.

84. At least as early as January 1998, despite available evidence showing that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally, GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn) healthcare practitioners including those in this Commonwealth, among others, as a safe treatment alternative for morning sickness in pregnant women.

85. In support of its off-label marketing efforts, at least as early as January 1998, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran to treat morning sickness.

86. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9 1999.)

87. GSK's promotional labeling under consideration included promotional statements relating the effectiveness of Zofran, such as "Zofran Can," "24-hour control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran.

88. In its March 9, 1999 letter, the FDA directed GSK to "**immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information**."

89. GSK disregarded this mandate by the FDA. For example, GSK's marketing as materials as early as 2000 in widely circulated in obstetrician and gynecology trade journals over-emphasized Zofran's "Pregnancy Category B" designation as an imprimatur of safeness for use in pregnancy on the very first page of the marketing material and without

adequate risk information. This created a false impression on the part of busy healthcare practitioners that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

90. When Zofran was first approved by the FDA to treat cancer patients, GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran sales to obstetricians and gynecologists by promoting Zofran as an established safe and effective treatment for morning sickness. GSK's initial strategy in this regard required its sales force to create new relationships with obstetricians and gynecologists by adding them as "new accounts." While this strategy had some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its other Division's already established relationships with obstetricians and gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran.

91. Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Healthcare division under which sales representatives from GSK's Consumer Healthcare division would market Zofran to obstetricians and gynecologists. At the time GSK's Consumer Healthcare sales force already had established relationships with, and routinely called on, obstetricians and gynecologists to promote and provide samples of another GSK product, Tums, specifically for the treatment and prevention of heartburn during pregnancy. GSK's established network for promoting Tums for use in pregnancy afforded it an efficient additional conduit for promoting Zofran for use in pregnancy.

92. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to obstetricians and gynecologists during GSK's Consumer Healthcare sales force's visits to obstetricians and gynecologists offices. Although some obstetricians and gynecologists performed surgeries and could order Zofran for post-operative nausea, the central focus of GSK's co-marketing effort was to promote Zofran for the much more common condition of morning sickness in pregnancy, and thus increase sales and profits.

93. GSK's Zofran sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether s/he attained or exceeded quarterly sales quotas. The more Zofran sold by a GSK sales representative or prescribed by a provider in that representative's sales territory, the greater his or her compensation and other incentives would be.

94. As a result of GSK's fraudulent marketing campaign, the precise details of which are uniquely within the control of GSK, Zofran achieved blockbuster status by 2002 and became the number one most prescribed drug for treating morning sickness in the United States. In 2002, sales of Zofran in the United States totaled $1.1 billion, while global Zofran sales were approximately $1.4 billion in 2002.

95. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012 the Department of Justice announced that GSK "agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs," which included Zofran among numerous others. *See* DOJ Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

96. Part of GSK's civil liability to the government included payments arising from the facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

97. GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. Another component of that plan led to a separate $150 million settlement between GSK and the United States in 2005. In or around 1993, a GSK marketing document sent to all of its

sales and marketing personnel nationwide advised that they should emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $__ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to personal profit. In this regard, GSK marketed Zofran beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers. GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled "Profit Maximization – It's in the Bag." Upon information and belief, GSK's conduct in this paragraph continued until the DOJ began investigating it in the early 2000s.

AUROBINDO DEFENDANTS

98. Under the ANDA process, the Code of Federal Regulations *required* the AUROBINDO DEFENDANTS to submit a label for ONDANSETRON, initially identical in all material aspects to the reference listed drug label.

99. Defendants AUROBINDO DEFENDANTS sell generic ONDANSETRON.

100. Defendants AUROBINDO DEFENDANTS did not investigate the accuracy of its ONDANSETRON drug label.

101. Defendants AUROBINDO DEFENDANTS did not review the medical literature for the ONDANSETRON drug.

102. Defendants AUROBINDO DEFENDANTS did not review the medical literature for the ONDANSETRON drug.

103. Defendants AUROBINDO DEFENDANTS are under a duty to ensure that its ONDANSETRON label is accurate

104. Defendants AUROBINDO DEFENDANTS relied upon the name brand manufacturer to review the aforementioned medical literature for the ONDANSETRON drug.

105. Defendants AUROBINDO DEFENDANTS relied upon the reference listed drug company for the reference listed ONDANSETRON drug to review the aforementioned medical literature.

106. Under the Code of Federal Regulations, Defendants AUROBINDO DEFENDANTS, as ANDA holders, had a duty to ensure its ZOFRAN, ONDANSETRON warnings to the medical community were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by ZOFRAN, ONDANSETRON or ONDANSETRON, to the medical community, Plaintiff's physician, Plaintiffs and other foreseeable users.

107. Under the Code of Federal Regulations, if Defendants AUROBINDO DEFENDANTS, as ANDA holders, discover information in the course of the fulfillment of its duties as outlined above, Defendants AUROBINDO DEFENDANTS must report that information to the medical community, Plaintiff's physician, Plaintiffs and other foreseeable users of ZOFRAN, and ONDANSETRON to ensure that its warnings are continually accurate and adequate.

108. Defendants AUROBINDO DEFENDANTS breached their duty to the medical community, Plaintiff's Physician, Plaintiff, and other foreseeable users similarly situated because they failed to ensure ZOFRAN, ONDANSETRON, warnings to the medical community, Plaintiff's physician, Plaintiff, other foreseeable users similarly situated were accurate and adequate.

109. Defendants AUROBINDO DEFENDANTS breached their duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because they failed to conduct post market safety surveillance of ZOFRAN, ONDANSETRON, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of ZOFRAN, ONDANSETRON.

110. Defendants AUROBINDO DEFENDANTS breached their duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by ZOFRAN, ONDANSETRON to the medical community, Plaintiff's physician, Plaintiffs and other like foreseeable users.

111. Defendants AUROBINDO DEFENDANTS breached their duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of ZOFRAN, and/or ONDANSETRON.

112. Defendants AUROBINDO DEFENDANTS breached their duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because they failed to report to the FDA *any* data (medical literature) concerning the risk and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing the active ingredient ONDANSETRON and/or ONDANSETRON.

113. Defendants AUROBINDO DEFENDANTS chose to rely on Defendant WYETH and its predecessors in interest, to keep abreast of current medical literature concerning ZOFRAN, ONDANSETRON and to inform them concerning its knowledge of how physicians were using ZOFRAN, ONDANSETRON and any dangers that were associated with that use, by properly reporting their knowledge to the FDA despite the fact that Defendants AUROBINDO DEFENDANTS knew, or should have known that WYETH and its predecessors in interest had a history of failing to adequately warn physicians about other dangerous products. Defendants AUROBINDO DEFENDANTS failed to exercise reasonable care to independently monitor their sales of ONDANSETRON and the medical literature, which would have alerted them to the fact that ZOFRAN, ONDANSETRON was widely over prescribed as a result of inadequate warnings in the package inserts and PDR monographs for ZOFRAN brand and generic ONDANSETRON. Defendants AUROBINDO DEFENDANTS also knew, or should have known in the exercise of reasonable care that the package insert for ZOFRAN, ONDANSETRON substantially understated the prevalence of acute side effects of ZOFRAN, ONDANSETRON and failed to use reasonable care to modify the package insert, and/or seek FDA approval to modify the package insert in order to adequately warn physicians and consumers.

FIRST CAUSE OF ACTION (NEGLIGENCE)

114. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

115. GSK had a duty to exercise reasonable care, and comply with existing standards of care, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

116. GSK failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

117. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and failed to comply with existing standards of care in the following acts and/or omissions:

a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Zofran for treating pregnant women while promoting the use of Zofran and providing kickbacks and financial incentives to health care professionals to convince health care professionals to prescribe Zofran for pregnancy-related nausea;

b. Marketing Zofran for the treatment of morning sickness in pregnant women without testing it determine whether or not Zofran was safe for this use;

c. Designing, manufacturing, producing, promoting, formulating, creating, and/or designing Zofran without adequately and thoroughly testing it;

d. Selling Zofran without conducting sufficient tests to identify the dangers posed by Zofran to pregnant women;

e. Failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Zofran for pregnant women;

f. Failing to evaluate available data and safety information concerning Zofran use in pregnant women;

g. Advertising and recommending the use of Zofran without sufficient knowledge as to its dangerous propensities to cause birth defects;

h. Representing that Zofran was safe for treating pregnant women, when, in fact, it was and is unsafe;

i. Representing that Zofran was safe and efficacious for treating morning sickness and hyperemesis gravidarum when GSK was aware that neither the safety nor efficacy for such treatment has been established;

j. Representing that GSK's animal studies in rats and rabbits showed no harm to fetuses, when the data revealed impairment of ossification (incomplete bone growth) and other signs of toxicity;

k. Failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;

l. Failing to accompany Zofran with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Zofran;

m. Failing to include a black box warning concerning the birth defects associated with Zofran;

n. Failing to issue sufficiently strengthened warnings following the existence of reasonable evidence associating Zofran use with the increased risk of birth defects;

o. Failing to advise Plaintiff, her healthcare providers, FDA, and the medical community that neither the safety nor the efficacy of Zofran for treating pregnancy-related nausea has been established and that the risks of the using the drug for that condition outweigh any putative benefit;

p. Failing to advise Plaintiff, her healthcare providers, FDA, and the medical community of clinically significant adverse reactions (birth defects) associated with Zofran use during pregnancy; and

q. Failing to correct its misrepresentations that the safety and efficacy of Zofran for treating morning sickness had been established.

118. Despite the fact that GSK knew or should have known that Zofran

significantly increased the risk of birth defects, GSK continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiff.

119. GSK knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

120. GSK's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiffs suffered and/or will continue to suffer.

121. Had Plaintiff Amanda Betty Sue Rousey not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Rousey would never have taken Zofran.

122. As a result of the foregoing acts and omissions, PEYTON BRYAN ROUSEY was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

123. Plaintiff Amanda Betty Sue Rousey also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

124. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Amanda Betty Sue Rousey is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

125. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

SECOND CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

126. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and

effect as if more fully set forth herein.

127. GSK is a merchant with respect to goods of the kind Plaintiffs received. GSK impliedly warranted that its product was merchantable. GSK impliedly warranted that its product was fit for the particular purpose of being used safely in the treatment of pregnancy- related nausea. Plaintiffs and their health care providers relied on GSK's skill, judgment and superior access to the drug's risk profile when deciding to use GSK's product.

128. GSK's product was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and instructions, and was unreasonably dangerous. GSK's product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Plaintiffs and their medical providers.

129. GSK breached its implied warranties because the product was not safe, not adequately packaged and labeled, did not conform to representations GSK made, and was not properly usable in its current form according to the labeling and instructions provided.

130. As a result of the foregoing acts and omissions, PEYTON BRYAN ROUSEY has suffered serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

131. As a result of the foregoing acts and omissions, A.S requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Amanda Betty Sue Rousey is informed and believes and further alleges that PEYTON BRYAN ROUSEY will in the future be required to obtain further medical and/or hospital care, attention, and services.

132. Plaintiff Amanda Betty Sue Rousey also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

133. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

134. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

135. GSK committed actual and constructive fraud. GSK committed actual fraud by misrepresenting material facts on which Plaintiffs and their healthcare providers acted. GSK committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence upon which Plaintiffs relied, and by failing to act, though it should have. GSK's conduct constitutes constructive fraud because GSK breached legal and equitable duties and violated its fiduciary relationships to patients and healthcare providers.

136. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiffs and their providers.

137. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiffs and their healthcare providers.

138. In violations of existing standards and duties of care, GSK made misrepresentations by means including, but not limited to, advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients and medical providers.

139. In violations of existing standards and duties of care, GSK intentionally, knowingly, falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Amanda Betty Sue Rousey and her providers, that:

a. Zofran was safe and effective for treating pregnancy-related nausea;

b. Zofran had been adequately tested and studied in pregnant women;

c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d. Zofran's "Pregnancy Category B" designation established safety and efficacy of Zofran for treating pregnancy-related nausea.

140. The representations made by GSK were material, false and misleading.

141. When GSK made these representations, it knew they were false.

142. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, including Plaintiffs and their providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy- related nausea.

143. At the time these representations were made by GSK and, at the time Plaintiff used Zofran, she was unaware of the falsity of said representations and reasonably believed them to be true.

144. In reasonable reliance upon said representations, Plaintiff's prescribers were induced to prescribe Zofran to her and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiff Amanda Betty Sue Rousey was induced to and did use Zofran to treat pregnancy- related nausea. Had GSK not made the foregoing express and implied false statements about the product, Plaintiffs would not have used the product and her medical providers would not have administered it and recommended it as safe.

145. GSK knew that Zofran had not been sufficiently tested for pregnancy-related nausea and that it lacked adequate warnings.

146. GSK knew or should have known that Zofran increases expectant mothers' risk of developing birth defects.

147. As a result of the foregoing acts and omissions, PEYTON BRYAN ROUSEY was caused to suffer birth defects that are permanent and lasting in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

148. Plaintiff Amanda Betty Sue Rousey also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

149. As a result of the foregoing acts and omissions, Plaintiffs require and will

require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Amanda Betty Sue Rousey is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

150. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

151. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

152. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiffs and their healthcare providers. GSK had exclusive access to material information about the teratogenic risks of Zofran, and GSK knew that neither Plaintiffs nor their medical providers could reasonably discover that information.

153. In violations of the existing standards and duties of care, GSK fraudulently concealed and intentionally omitted material facts in representations by means including, but not limited to advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients, medical providers, and the FDA.

154. In violations of the existing standards and duties of care, in representations to Plaintiff's healthcare providers, expectant mothers including Plaintiffs and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

a. GSK was illegally paying and offering remuneration and promoting financial incentives to providers to encourage them to promote and prescribe Zofran;

b. GSK had not and has not conducted any studies establishing the safety or efficacy of Zofran treatment in pregnant women;

c. *in utero* Zofran exposure increases the risk of birth defects;

d. independent researchers have reported in peer-reviewed literature that *in utero* Zofran exposure increases the risk of birth defects;

e. the risks of birth defects associated with the consumption of Zofran by pregnant women were not adequately tested prior to GSK's marketing of Zofran;

f. the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;

g. Zofran is not safe and effective for treating pregnancy-related nausea; and

h. GSK's internal data and information signaled an association between Zofran use during pregnancy with birth defects.

155. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea misled physicians, hospitals and healthcare providers, and expectant mothers including Plaintiff Amanda Betty Sue Rousey and her providers into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

156. GSK knew that physicians, hospitals, healthcare providers and expectant mothers such as Plaintiff had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran, as set forth herein.

157. Plaintiffs and healthcare providers reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently and/or purposefully omitted material facts. Had GSK disclosed the material omissions about the product, Plaintiffs would not have used the product and her providers would not have prescribed it and at a minimum would have communicated to Plaintiff the pregnancy risks and how to avoid them.

158. As a result of the foregoing acts and omissions, PEYTON BRYAN ROUSEY was caused to suffer serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

159. Plaintiff Amanda Betty Sue Rousey also has sustained severe emotional

distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

160. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Amanda Betty Sue Rousey is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

161. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

FIFTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

162. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

163. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiffs and their healthcare providers.

164. In violation of the existing standards and duties of care, GSK materially misrepresented and omitted complete and accurate information in Zofran's labeling, advertising, marketing, sales and marketing persons, notices, oral promotional efforts, and product information concerning the nature, character, quality, safety, and proper use of their product. Specifically, these misrepresentations GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiffs and their healthcare providers, include, but are not limited to the following:

a. Zofran was safe and effective for treating pregnancy-related nausea;

b. Zofran had been adequately tested and studied in pregnant women;

c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d. Zofran's "Pregnancy Category B" designation established the safety and

efficacy of Zofran for treating pregnancy-related nausea.

165. The representations made by GSK were, in fact, false and misleading.

166. Plaintiffs and their providers reasonably relied upon GSK's expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, of merchantable quality and fit for use during pregnancy. In justifiable reliance upon these misrepresentations, Plaintiffs and their providers were induced to prescribe and use GSK's product.

167. Had GSK not made express and implied false statements, or revealed all material information about Zofran, Plaintiffs would not have used the product and her providers would not have prescribed it.

168. As a result of the foregoing acts and omissions, PEYTON BRYAN ROUSEY has suffered serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

169. As a result of the foregoing acts and omissions, A.S requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Amanda Betty Sue Rousey is informed and believes and further alleges that PEYTON BRYAN ROUSEY will in the future be required to obtain further medical and/or hospital care, attention, and services.

170. Plaintiff Amanda Betty Sue Rousey also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

171. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

SIXTH CAUSE OF ACTION
(DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION ACT, M.G.L. c. 93A, VIOLATIONS)

172. Plaintiffs repeat, reiterate and reallege each and every allegation of this

Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

173. GSK engaged in trade and commerce within the Commonwealth of Massachusetts.

174. The same actions that constitute GSK's negligence, breach of warranty, misrepresentations and concealment constitute a violation of M.G.L. c. 93A.

175. As described herein, GSK represented that its product had characteristics, uses, and benefits that it did not have.

176. As described herein, GSK represented that its product was of a particular standard, quality, and grade that they either knew or should have known was not of the standard, quality, or grade described.

177. GSK failed to provide accurate disclosures of all material information before Plaintiffs and their providers transacted to use GSK's product.

178. GSK's willful and knowing withholding of important safety information and critical product information constitutes a violation of M.G.L. c. 93A.

179. GSK actively, knowingly, and deceptively concealed its knowledge of its product's dangerous properties and risks. This conduct evidences bad faith and unfair and deceptive practices.

180. GSK engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

181. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise and caused substantial injury to consumers. In this regard, GSK engaged in an unconscionable course of action.

182. GSK willfully, wantonly, recklessly, and with gross negligence, engaged in the conduct described herein, which it knew was deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

183. GSK's conduct and practices described herein are in violation of M.G.L. c. 93A.

184. Plaintiffs have provided a written demand for relief to GSK pursuant to the provisions of M.G.L. c. 93A § 9 and has otherwise complied with the requirements of the statute.

185. GSK is liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs, resulting from this unfair and deceptive conduct, including multiple damages.

SEVENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM, M.G.L. c. 231 §85X)

186. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

187. As a direct and proximate result of Defendant's negligence and wrongful conduct, Ms. Rousey has been deprived of the society, love, affection, companionship, care and services, of her child, PEYTON BRYAN ROUSEY, and is entitled to recovery for said loss pursuant to G. L. c. 231, § 85X.

188. Plaintiffs seek all damages available against GSK on account of her loss of her daughter's consortium.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against GSK on each of the above-referenced claims and Causes of Action and as follows:

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For full refund of all purchase costs of Zofran;

e) For consequential damages in excess of the jurisdictional minimum of this Court;

f) For compensatory damages in excess of the jurisdictional minimum of this Court;

g) For multiplication of damages pursuant to M.G.L. c. 93A;

h) For attorneys' fees, expenses and costs of this action; and

i) For such further and other relief as this Court deems necessary, just and proper.

Dated: July 2, 2015

Respectfully submitted,

MATTHEWS & ASSOCIATES

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